

<http://www.coe.int/pharmacrime>



Strasbourg, 25 June 2009  
pc-isp/Docs 2009/pc-isp (2009) 02EN

PC-ISP (2009) 2

**AD HOC COMMITTEE ON COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES**  
**INVOLVING THREATS TO PUBLIC HEALTH**  
**(PC-ISP)**

Draft Convention  
of the Council of Europe  
on counterfeiting of medical products  
and similar crimes involving threats to public health

Revised following the debates during the 1st meeting of PC-ISP  
Document prepared by the Directorate General of Human Rights and Legal Affairs

**Preamble**

The member states of the Council of Europe and the other signatories to this Convention,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members;

Noting that the counterfeiting of medical products and similar crimes, seriously endanger public health;

Recalling the Action Plan adopted at the 3<sup>rd</sup> Summit of Heads of State and Government of the Council of Europe (Warsaw, 16-17 May 2005), which recommends the development of measures to strengthen the security of European citizens;

Bearing in mind the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950, CETS No. 5), the Convention on the Elaboration of a European Pharmacopoeia (1964, CETS No.50) and its Protocol (1992, CETS No. 134), the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997, CETS No. 164) and the Additional Protocols thereto (1998, CETS No. 168, 2002, CETS No.186 and 2005, CETS No. 195) and the Convention on Cybercrime (2004, CETS No. 185);

Also bearing in mind the other relevant work of the Council of Europe, particularly the decisions of the Committee of Ministers and work of the Parliamentary Assembly, notably Resolution AP(2001)2 concerning the pharmacist's role in the framework of health security, the replies adopted by the Committees of Ministers on 6 April 2005 and on 26 September 2007, respectively, concerning Parliamentary Assembly Recommendations 1673 (2004) on "Counterfeiting: problems and solutions", and 1794 (2007) on "The quality of medicines in Europe";

Having due regard to other relevant international legal instruments and programmes, conducted notably by the World Health Organisation in particular the work of the group IMPACT, and by the European Union, notably Directive 2004/27/EC of the European Parliament and the Council, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use and of Directive 2004/28/EC of the European Parliament, amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products;

Determined to contribute effectively to the attainment of the common goal of combating crime involving counterfeiting of medical products and similar crimes involving threats to public health, by introducing notably new offences and penal sanctions relative to these offences;

Taking into account the need to prepare a comprehensive international instrument which is centred on the aspects linked to prevention, protection of victims and with criminal law in combating all forms of counterfeiting of medical products and similar crimes involving threats to public health, and which sets up a specific monitoring mechanism;

Have agreed as follows:

## Chapter I – Purposes, principle of non-discrimination, scope, definitions

### Article 1 – Purposes

1. The purposes of this Convention are to prevent and combat threats to public health by:
  - a. providing for the criminalisation of certain acts, cf. Articles 5, 6 and 7 of this Convention;
  - b. protecting the rights of victims of the offences established under this Convention;
  - c. promoting national and international co-operation.
2. In order to ensure effective implementation of its provisions by the Parties this Convention sets up a specific monitoring mechanism.

### Article 2 – Principle of non-discrimination

The implementation of the provisions of this Convention by the Parties, in particular the enjoyment of measures to protect the rights of victims, shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or any other opinion, national or social origin, association with a national minority, property, birth, sexual orientation, state of health, disability or other status.

### Article 3 – Scope

This Convention concerns medical products whether they are patent protected or protected by a trademark, or not, or whether they are generic or not as well as the ingredients and parts or materials designated to be used in the production of medical products, including accessories designated to be used together with medical devices.

**Deleted:** components

**Deleted:** to be used

### Article 4 – Definitions

For the purposes of this Convention:

- a. the term “medical product” shall mean medicinal products and medical devices;
- b. the term “medicinal product” shall mean medicines for human and veterinary use, which may be:
  - i. any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;
  - ii. any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;
  - iii. an investigational medicinal product.
- c. the term “ingredients” shall mean substances, irrespective of origin, designated to be used as active substances or excipients for the production of medicinal products for human or veterinary use;
- d. the term “medical device” shall mean any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:

**Deleted:** the term “counterfeit medical product, ingredient or component” shall mean a medical product, ingredient or component with a false representation of its identity and/or source;

**Formatted:** Bullets and Numbering

**Formatted:** Bullets and Numbering

**Deleted:** that are

**Deleted:** intended

**Deleted:** intended

- i. diagnosis, prevention, monitoring, treatment or alleviation of disease,
- ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- iii. investigation, replacement or modification of the anatomy or of a physiological process,
- iv. control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

e. the term “accessory” shall mean an article which whilst not being a device is designated specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

**Formatted:** Bullets and Numbering

f. the terms “parts” and “materials” shall mean all parts and materials constructed and designated to be used for medical devices;

**Deleted:** components

**Deleted:** materials and

**Deleted:** parts

**Deleted:** used

g. the term “document related to a medical product, an ingredient, a part or a material” shall mean any document, including the packaging, accompanying, or directly associated with the manufacturing and/or distribution thereof;

**Deleted:** in the construction/assembling of

**Deleted:** or component

h. the term “manufacturing” shall mean:

**Deleted:** at least

i. as regards a medicinal product, any part of the process of producing the medicinal product, or an ingredient of such a product, or of bringing the medicinal product or ingredient to its final state;

ii. as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;

**Deleted:** . This includes procurement of materials, processing, assembling, packaging, labelling, storage, sterilizing, testing and releasing for supply of the medicinal product or of any ingredient of the medicinal product as part of that process, the design or manufacturing by a third party as well as the re-packaging or relabeling of a medicinal product.

iii. as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to their final state;

i. the term “counterfeit” shall mean a false representation as regards identity and/or source;

**Deleted:** as regards a medical device, the designing and/or manufacturing, packaging and labelling by any natural or legal persons of a medical device with the intention of making the finished medical device available for use under their name, whether or not such a medical device is designed and/or manufactured by these persons themselves or on their behalf by a third party.

j. the term “victim” shall mean a natural person having suffered adverse physical or psychological effects as a result of having used counterfeit or illicitly manufactured or illicitly supplied medical products.

**Chapter II – Substantive criminal law**

**Article 5 – Counterfeiting of medical products, ingredients, parts or materials, as well as accessories and related crimes**

**Formatted:** Bullets and Numbering

**Deleted:** or components

- 1. Each Party shall take the necessary legislative or other measures to ensure that the following acts, when committed intentionally, are criminalised:

- a. the manufacturing of counterfeit medical products, ingredients, parts or materials, as well as accessories, including their adulteration; **Deleted:** or components
- b. the counterfeiting of any document related to medical products, ingredients, parts or materials, as well as accessories; **Deleted:** falsifying  
**Deleted:** or component
- c. the supplying or offering to supply of counterfeit medical products, ingredients, parts or materials, as well as accessories; **Deleted:** or components
- d. the advertising [to the general public or to professionals] with the intention to promote the supply of counterfeit medical products; **Deleted:** promotion  
**Deleted:** of counterfeit medical products, ingredients or components
- e. the trafficking in counterfeit medical products, ingredients, parts or materials, as well as accessories. **Deleted:** illicit  
**Deleted:** or component

2. Each Party shall take the necessary legislative or other measures to criminalise, when committed intentionally, the possession of a counterfeit medical product, a counterfeit active substance or counterfeit parts or materials, as well as a counterfeit accessory, with the intention of manufacturing, supplying, offering to supply or trafficking thereof.

**Deleted:** Each Party shall take the necessary legislative or other measures to establish as a criminal offence, when committed intentionally, the possession of a counterfeit medical product, ingredients or components as well as documents related to medical products, ingredients and components, for the purpose of committing any of the offences set out in paragraph 1.

**Article 6 – Illicit manufacturing or supplying of medical products**

Each Party shall take the necessary legislative or other measures to ensure that, in so far as such conduct is not covered by Article 5, illicit manufacture and illicit supply of medical products which have a potential [serious] risk to public or individual health, when committed intentionally, are criminalised.

**Deleted: Unauthorised**  
**Deleted: non-counterfeit**  
**Deleted: , ingredients and components**  
**Deleted:** in accordance with its internal legal system, to ensure that the following acts, when committed intentionally, are subject to criminal and/or other measures:

**Article 7 – Aiding or abetting and attempt**

- 1. Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention.
- 2. Each Party shall adopt such legislative and other measures as may be necessary to criminalise an attempt, when committed intentionally, to commit any of the offences established in accordance with this Convention.

**Deleted:** ¶  
a) the manufacturing, without authorisation and/or in breach of the standards for quality, safety and efficacy as required by the internal law of the Party, of non-counterfeit medical products, ingredients and components¶  
¶  
b) the supplying or offering to supply, without authorisation and/or in breach of the standards for quality, safety and efficacy as required by the internal law of the Party, non-counterfeit medical products, ingredients and components. ¶

**Article 8 – Jurisdiction**

- 1. Each Party shall adopt such legislative and other measures as may be necessary to establish jurisdiction over any offence established in accordance with this Convention, when the offence is committed:
  - a. in its territory; or
  - b. on board a ship flying the flag of that Party; or
  - c. on board an aircraft registered under the laws of that Party; or
  - d. by one of its nationals; or
  - e. by a person habitually residing in its territory.

**Deleted:** establish as a criminal offence

**Deleted:** <#>Each Party may reserve the right not to apply the whole or part of paragraph 2 of this Article.¶

2. For the prosecution of the offences established in accordance with Article 5, paragraph 1, sub-paragraphs ~~a, to c, in conjunction with Article 11, paragraphs a, e, and f, of this Convention~~, each Party shall adopt such legislative and other measures as may be necessary to ensure that the establishment of its jurisdiction under sub-paragraph d. of paragraph 1 is not subject to the condition that the acts are criminalised at the place where they were committed, or a denunciation by the State where the acts were committed.
3. Each Party shall adopt such legislative and other measures as may be necessary to establish jurisdiction over any criminal offence established in accordance with this Convention, when the offence is committed against one of its nationals or a person habitually resident in its territory.
4. Each Party shall adopt such legislative and other measures as may be necessary to establish jurisdiction over any offence established in accordance with this Convention, when the alleged offender is present in its territory and cannot be extradited to another Party because of his or her nationality.
5. Each Party may, at the time of signature or when depositing its instrument of ratification, acceptance, approval or accession, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply or to apply only in specific cases or conditions the jurisdiction rules laid down in paragraph 1, sub-paragraphs d, and e, and paragraphs 2, 3, and 4, of this Article.
6. Where more than one Party claims jurisdiction over an alleged offence established in accordance with this Convention, the Parties concerned shall consult, where appropriate, with a view to determining the most appropriate jurisdiction for prosecution.
7. Without prejudice to the general rules of international law, this Convention shall not exclude any criminal jurisdiction exercised by a Party in accordance with its national law.

**Deleted:** , b, and

**Deleted:** and Article 6

### **Article 9 – Corporate liability**

1. Each Party shall adopt such legislative and other measures as may be necessary to ensure that legal persons can be held liable for offences established in accordance with this Convention, when committed for their benefit by any natural person, acting either individually or as part of an organ of the legal person, who has a leading position within it based on:
  - a. a power of representation of the legal person;
  - b. an authority to take decisions on behalf of the legal person;
  - c. an authority to exercise control within the legal person.
2. In addition to the cases already provided for in paragraph 1, each Party shall adopt such legislative and other measures as may be necessary to ensure that a legal person can be held liable where the lack of supervision or control by a natural person referred to in paragraph 1 has made possible the commission of an offence established in accordance with this Convention for the benefit of that legal person by a natural person acting under its authority.
3. Subject to the legal principles of the Party, the liability of a legal person may be criminal, civil or administrative.

4. Such liability shall be without prejudice to the criminal liability of the natural persons who have committed the offence.

#### **Article 10 – Sanctions and measures**

1. Each Party shall adopt such legislative and other measures as may be necessary to ensure that the offences established in accordance with this Convention are punishable by effective, proportionate and dissuasive sanctions taking account of their seriousness. These sanctions shall include penalties involving deprivation of liberty that may give rise to extradition.
2. Each Party shall adopt such legislative and other measures as may be necessary to ensure that legal persons held liable in accordance with Article 9 are subject to effective, proportionate and dissuasive sanctions including criminal or non-criminal monetary sanctions and may include other measures such as:
  - a. temporary or permanent disqualification from exercising commercial activity;
  - b. placing under judicial supervision;
  - c. a judicial winding-up order.
3. Each Party shall adopt such legislative and other measures as may be necessary
  - a. to permit the destruction of medical products resulting from the offences established in Articles 5 and 6 of this Convention;
  - b. to permit seizure and confiscation of:
    - i. goods, documents and other instrumentalities used to commit the offences established in accordance with this Convention or to facilitate their commission;
    - ii. proceeds of these offences, or assets whose value corresponds to such proceeds.
  - c. to permit the total or partial closure, temporarily or permanently, of any establishment used to commit any of the offences established in accordance with this Convention, without prejudice to the rights of bona fide third parties, or to disqualify the perpetrator temporarily or permanently from exercising the commercial or professional activity in connection with which they were committed, including by withdrawing licenses, where the perpetrators have abused the confidence placed in them in their professional capacities or are holding authorisation to manufacture and supply medical products;

#### **Article 11 – Aggravating circumstances**

Each Party shall adopt such legislative or other measures as may be necessary to ensure that the following circumstances, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of national law, be taken into consideration as aggravating circumstances in determining the sanctions in relation to the offences established in accordance with this Convention:

- a. the offence caused the death of, or damage to the physical or mental health of, the victim;

- b. the offence was committed by persons abusing the confidence placed in them in their professional capacity or persons holding authorisation to manufacture and supply medical products, ingredients and parts or materials, as well as accessories;
- c. the offences of advertising and supplying were committed having resort to means of large scale distribution;
- d. [the offence was committed by several people acting together]
- e. the offence was committed in the framework of a criminal organisation;
- f. the perpetrator has previously been convicted of offences of the same nature.

Deleted: components

Deleted: promotion

Deleted: mass

#### Article 12 – Previous convictions

Each Party shall adopt such legislative or other measures as may be necessary to provide for the possibility to take into account final sentences passed by another Party in relation to the offences of the same nature when determining the sanctions.

### Chapter III – Investigation, prosecution and procedural law

#### Article 13 – Initiation and continuation of proceedings

Each Party shall adopt such legislative or other measures as may be necessary to ensure that investigations or prosecution of offences established in accordance with this Convention should not be subordinate to a complaint and that the proceedings may continue even if the complaint is withdrawn.

#### Article 14 – Criminal investigations

1. Each Party shall adopt such measures as may be necessary to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.
2. Each Party shall adopt such legislative or other measures as may be necessary, in conformity with the fundamental principles of its national law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques such as electronic and other forms of surveillance as well as infiltration operations by its competent authorities.

Deleted: asset

### Chapter IV – Collaborating authorities and information exchange

#### Article 15 – National measures of co-ordination, collaboration and information exchange

1. Each Party shall adopt such legislative or other measures as may be necessary to ensure that representatives of regulatory authorities in the health sphere, customs, police and the judicial authorities exchange information, assist each other in and co-ordinate preventive

and repressive action in accordance with national law in order to combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.

Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.

2. With due respect for the requirements of the protection of personal data, each Party shall adopt such legislative or other measures as may be necessary to set up or strengthen mechanisms for:
  - a. receiving information and data, collection or focal points, at the national or local levels and in collaboration with private sector and civil society, for the purpose of taking preventive and repressive action, observing, evaluating and comparison of phenomena related to counterfeiting of medical products and similar crimes involving threats to public health;
  - b. making available the respective information and data obtained within each of the regulatory authorities in the health sphere, customs, police and the judicial authorities for the collaboration between the authorities.
3. Each Party shall adopt such measures as may be necessary to ensure that persons, units or services in charge of coordination, collaboration and information exchange are trained for this purpose. Such units or services shall have adequate resources.

**Deleted:** Each

**Deleted:** with due respect for the requirements of the protection of personal data

## Chapter V – Measures for prevention

### Article 16 – Preventive measures

1. Each Party shall adopt such legislative or other measures as may be necessary to establish norms on the manufacturing and supply of medical products, ingredients and parts or materials, as well as accessories. These norms shall address, in particular:
  - a. standards for quality, safety and efficacy;
  - b. the authorisations and certificates required under its internal law;
  - c. the supervision of all professional activities within the distribution chain from manufacturing to supplying of medical products, ingredients and parts or materials, as well as accessories to the end-user.
2. Each Party shall, as appropriate and where applicable, establish co-operation with the pharmaceutical and medical device sectors, to introduce adequate track and change systems on medical products, ingredients and parts or materials, as well as accessories.
3. With the aim of preventing counterfeiting of medical products, ingredients and parts or materials, as well as accessories, each Party shall take the necessary measures to provide, inter alia, for:
  - a. training of health care professionals, providers, police and customs authorities as well as relevant regulatory authorities;
  - b. the promotion of awareness raising campaigns addressed to the general public providing information about counterfeit medical products, with the involvement of relevant non-governmental organisations and the media;

**Deleted:** components

**Deleted:** components

**Deleted:** components

**Deleted:** components

- c. the development of agreements with Internet Service Providers and Domain Name Registrars to facilitate action against websites acting illegally in the promotion or supplying of counterfeit medical products, ingredients and parts or materials, as well as accessories.

Deleted: components

## Chapter VI – Measures for protection

### Article 17 – Protection of victims

1. Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims, in particular by:
  - a. ensuring that victims have access to information relevant to their case and which is necessary for the protection of their health;
  - b. assisting victims in their physical, psychological and social recovery;
  - c. providing, in its internal law, for the right of victims to compensation from the perpetrators.

### Article 18 – The standing of victims in criminal investigations and proceedings

1. Each Party shall take the necessary legislative or other measures to protect the rights and interests of victims at all stages of criminal investigations and proceedings, in particular by:
  - a. informing them of their rights and the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the charges, the general progress of the investigation or proceedings, and their role therein as well as the outcome of their cases;
  - b. enabling them, in a manner consistent with the procedural rules of internal law, to be heard, to supply evidence and to choose the means of having their views, needs and concerns presented, directly or through an intermediary, and considered;
  - c. providing them with appropriate support services so that their rights and interests are duly presented and taken into account;
  - d. providing effective measures for their safety, as well as that of their families and witnesses on their behalf, from intimidation and retaliation.
2. Each Party shall ensure that victims have access, as from their first contact with the competent authorities, to information on relevant judicial and administrative proceedings.
3. Each Party shall ensure that victims have access, provided free of charge where warranted, to legal aid when it is possible for them to have the status of parties to criminal proceedings.
4. Each Party shall provide, by means of legislative or other measures, in accordance with the conditions provided for by its internal law, the possibility for groups, foundations, associations or governmental or non-governmental organisations, to assist and/or support the victims with their consent during criminal proceedings concerning the offences established in accordance with this Convention.

Deleted: criminal

Deleted: General measures of protection

Deleted: criminal

## Chapter VII – International co-operation

### Article 19 – International co-operation in criminal matters

1. The Parties shall co-operate with each other, in accordance with the provisions of this Convention and in pursuance of relevant applicable international and regional instruments and arrangements agreed on the basis of uniform or reciprocal legislation and their national law, to the widest extent possible, for the purpose of investigations or proceedings concerning the offences established in accordance with this Convention, including seizure and confiscation.
2. Each Party shall adopt such legislative or other measures as may be necessary to ensure that victims of an offence established in accordance with this Convention committed in the territory of a Party other than the one where they reside can make a complaint before the competent authorities of their state of residence.
3. If a Party that makes mutual legal assistance in criminal matters or extradition conditional on the existence of a treaty receives a request for legal assistance or extradition from a Party with which it has not concluded such a treaty, it may consider this Convention the legal basis for mutual legal assistance in criminal matters or extradition in respect of the offences established in accordance with this Convention.

### Article 19bis – International co-operation on prevention and other administrative measures

1. The Parties shall co-operate on protecting and providing assistance to victims.
2. The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.
3. Each Party shall endeavour to integrate, where appropriate, prevention and combating of the counterfeiting of medical products and similar crimes involving threats to public health into assistance or development programmes provided for the benefit of third states.

**Deleted:** General principles and measures for international co-operation

**Deleted:** ¶  
<#>¶  
<#>preventing and combating the counterfeiting of medical products similar crimes involving threats to public health protecting and providing assistance to victims;¶  
¶

**Deleted:** .

**Formatted:** Bullets and Numbering

**Deleted:** The Parties shall, without prejudice to their internal reporting systems, designate a national<sup>1</sup> contact point which shall be responsible for transmitting<sup>2</sup> requests for information and/or cooperation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.¶  
¶

**Formatted:** Bullets and Numbering

**Deleted:** <#>Each Party shall endeavour to integrate, where appropriate, prevention and combating of the counterfeiting of medical products and similar crimes involving threats to public health into assistance or development programmes provided for the benefit of third states.¶

## Chapter VIII – Monitoring mechanism

### Article 20 – Committee of the Parties

1. The Committee of the Parties shall be composed of representatives of the Parties to the Convention.
2. The Committee of the Parties shall be convened by the Secretary General of the Council of Europe. Its first meeting shall be held within a period of one year following the entry into force of this Convention for the tenth signatory having ratified it. It shall subsequently meet whenever at least one third of the Parties or the Secretary General so requests.

3. The Committee of the Parties shall adopt its own rules of procedure.

#### **Article 21 – Other representatives**

1. The Parliamentary Assembly of the Council of Europe, the European Committee on Crime Problems (CDPC), the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), the Commission of the European Pharmacopoeia, the European Directorate for the Quality of Medicines and Healthcare (EDQM) and its Advisory Group of the General European Network of Official Medicines Control Laboratories (GeON), as well as other relevant Council of Europe intergovernmental committees, shall each appoint a representative to the Committee of the Parties in order to contribute to a multisectoral and multidisciplinary approach.
2. The Committee of Ministers may invite other Council of Europe bodies to appoint a representative to the Committee of the Parties after consulting the latter.
3. Representatives of civil society, and in particular non-governmental organisations, may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
4. Representatives appointed under paragraphs 1 to 3 above shall participate in meetings of the Committee of the Parties without the right to vote.

Deleted: ensure

#### **Article 22 – Functions of the Committee of the Parties**

1. The Committee of the Parties shall monitor the implementation of this Convention. The rules of procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention, using a multisectoral and multidisciplinary approach.
2. The Committee of the Parties shall facilitate the collection, analysis and exchange of information, experience and good practice between States to improve their capacity to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health.
3. The Committee of the Parties shall also, where appropriate:
  - a. facilitate the effective use and implementation of this Convention, including the identification of any problems and the effects of any declaration or reservation made under this Convention;
  - b. express an opinion on any question concerning the application of this Convention and facilitate the exchange of information on significant legal, policy or technological developments;
  - c. make specific recommendations to Parties concerning the implementation of this Convention.
4. The Committee of the Parties shall be assisted by the Secretariat of the Council of Europe in carrying out its functions pursuant to this article.
5. The European Committee on Crime Problems (CDPC) shall be kept periodically informed regarding the activities mentioned in paragraphs 1, 2 and 3 of this article.

Formatted: Bullets and Numbering

## **Chapter IX – Relationship with other international instruments**

### **Article 23 – Relationship with other international instruments**

1. This Convention shall not affect the rights and obligations arising from the provisions of other international instruments to which Parties to the present Convention are Parties or shall become Parties and which contain provisions on matters governed by this Convention.
2. The Parties to the Convention may conclude bilateral or multilateral agreements with one another on the matters dealt with in this Convention, for purposes of supplementing or strengthening its provisions or facilitating the application of the principles embodied in it.

## **Chapter X – Amendments to the Convention**

### **Article 24 – Amendments**

1. Any proposal for an amendment to this Convention presented by a Party shall be communicated to the Secretary General of the Council of Europe and forwarded by him or her to the member States of the Council of Europe, any signatory, any State Party, the European Community, any State invited to sign this Convention in accordance with the provisions of Article 25, paragraph 1, and any State invited to accede to this Convention in accordance with the provisions of Article 26, paragraph 1.
2. Any amendment proposed by a Party shall be communicated to the European Committee on Crime Problems (CDPC), which shall submit to the Committee of Ministers its opinion on that proposed amendment.
3. The Committee of Ministers shall consider the proposed amendment and the opinion submitted by the CDPC and, following consultation with the non-member States Parties to this Convention, may adopt the amendment.
4. The text of any amendment adopted by the Committee of Ministers in accordance with paragraph 3 of this Article shall be forwarded to the Parties for acceptance.
5. Any amendment adopted in accordance with paragraph 3 of this Article shall enter into force on the first day of the month following the expiration of a period of one month after the date on which all Parties have informed the Secretary General that they have accepted it.

## **Chapter XI – Final clauses**

### **Article 25 – Signature and entry into force**

1. This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration as well as the European Community.
2. This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.
3. This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which 5 signatories, including at least

3 member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of the preceding paragraph.

4. In respect of any State referred to in paragraph 1 or the European Community, which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

#### **Article 26 – Accession to the Convention**

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties to this Convention and obtaining their unanimous consent, invite any non-member State of the Council of Europe, which has not participated in the elaboration of the Convention, to accede to this Convention by a decision taken by the majority provided for in Article 20.d of the Statute of the Council of Europe, and by unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.
2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

#### **Article 27– Territorial application**

1. Any State or the European Community may, at the time of signature or when depositing its instrument of ratification, acceptance, approval or accession, specify the territory or territories to which this Convention shall apply.
2. Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.
3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

#### **Article 28 – Reservations**

No reservation may be made in respect of any provision of this Convention, with the exception of the reservations expressly established. Any reservation may be withdrawn at any time.

#### **Article 29 – Friendly settlement**

The European committee on crime problems will follow the application of this convention and facilitate, when necessary, the friendly settlement of all difficulties related to its application.

#### **Article 30 – Denunciation**

1. Any Party may, at any time, denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.
2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

#### **Article 31 – Notification**

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, any State signatory, any State Party, the European Community, any State invited to sign this Convention in accordance with the provision of Article 25 and any State invited to accede to this Convention in accordance with the provisions of Article 26 of:

- a. Any signature;
- b. The deposit of any instrument of ratification, acceptance, approval or accession;
- c. Any date of entry into force of this Convention in accordance to Articles 25 and 26;
- d. Any amendment adopted in accordance with Article 24 and the date on which such an amendment enters into force;
- e. Any reservation made under Articles 7 and 8;
- f. Any denunciation made in pursuance of the provisions of Article 30;
- g. Any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done in...., this.....in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention, to the European Community and to any State invited to accede to this Convention.